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## FOOD AND DRUG ADMINISTRATION (FDA) CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

Antiviral Drugs Advisory Committee (AVDAC)
Hilton Hotel, Washington DC/Silver Spring
8727 Colesville Road, Silver Spring, MD
June 2, 2010

## **Questions to the Advisory Committee**

The committee will discuss biologics license application (BLA) 125283, motavizumab, single-dose liquid solution 50 mg/0.5 milliliter (mL) and 100 mg/1 mL vials, MedImmune, LLC, for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease.

- 1) Please comment on the safety profile of motavizumab, specifically with respect to the potential for hypersensitivity reactions including life-threatening anaphylaxis.
- 2) Do the data from the applicant's studies adequately support the efficacy of motavizumab for the prevention of serious lower respiratory tract infection with RSV in at risk infants?
- 3) Given the potential benefits and risks, should motavizumab be licensed for marketing?

**Vote:** Yes/No/Abstain

Please discuss the rationale for your vote.

- 1. If no, what additional data/studies can be provided to support the licensing of motavizumab?
- 2. If yes, are there post-marketing studies needed to provide data that would aid in safer or more optimal use of motavizumab?